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Paper No: 20
Appeal No: 2002-1816
Appellant: KHETANI VIKRAM
Application: 09/283,645

Board of Patent Appeals and Interferences
Docketing Notice

Application 09/283,645 was received from the Technology Center at the Board on June 10, 2002 and has been assigned Appeal No: 2002-1816.

A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on:	March 20, 2002
Reply Brief filed on:	None
Request for Hearing filed on:	None

In all future communications regarding this appeal, please include both the application number and the appeal number.

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Paper No. 19

Application Number: 09/283,645

Filing Date: April 1, 1999

Appellant(s): Khestani et al.

Joseph Lucci

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 20, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

1. Whether anticipation was found for generic claims 1 and 15 by Jursic when the scope of the claims are given their broadest reasonable interpretation per MPEP 2111?
2. Whether in view of the conventional teaching disclosed in the prior art, one skilled in racemic material separation art would found the limitations of the dependent claims prima facie obvious?
3. Whether the instant claims being broader are obvious type double patenting over claims 1-9 of US 5,936,091 issued as parent application, based on the judicially created doctrine of obviousness type double patenting ?

(7) Grouping of Claims

The rejection of claims 1-8, 10-13 and 15 stand or fall together as appellant's brief stated.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims on appeal.

US 4,410,700	Rice	Oct. 1983

Jursic et al. "Determination of enantiomeric composition of 1-phenyl-2(2-piperidinyl-acetamide" Tetrahedron:assymetry v.5, 1711-1716 (1994)

Patrick et al. "Synthesis of deuterium labeled methylphenidate..." J. Label. Comp. Pharm. V.9, p. 485-490 (1982)

Berrang et al. "Enantiomeric amonopropiophenones" CA 97:38738 (1982)

Ohashi et al. "Acylaminonaphthanlene derivatives" CA 102;186157 (1985)

Vanderplas et al. "A convenient synthesis of cis-benal-hydrocylmethyl cyclohexlamine" CA 118:101538 (1992)

Morrison and Boyd "Organic Chemistry" Allyn and Bacon, p.32-34 (1973)

(10) Grounds of Rejection

The following grounds of rejection which were made in Paper No.10 are applicable to the appealed claims:

(A)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jursic et al.

Jursic et al. Disclosed process of the claims i.e. the exact compound in the enantiomeric forms, the acidic resolving agents (see p.1712-1713 structure and acidic functionality) and the salt complex (see p.1713 the complex of the acidic resolving agent and the amide compound is the formation of hydrogen bonding, acidic--H--N--base, i.e. an amine salt).

(B)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. in view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118.

Jursic et al. disclosed process of separating enantiomeric isomers of the claims by formation of the racemic compounds with a chiral resolving agent (see p 1712-1713) in an organic solvent (see p 1713). The difference between the claims and Jursic is that instead of the chiral resolving agents disclosed on p.1712, applicants used an alternative conventional chiral resolving agent. The well recognition of the claimed chiral resolving agents are found in Berrang et al., Ohashi et al. or Vanderplas et al. wherein enantiomeric amino compounds are resolved into stereo isomeric forms through formation of a stereo

specific complex between the compounds and the chiral agent. One having ordinary skill in the art would be motivated to employ these conventional chiral resolving agents for separation of enantiomers knowing that such isomers have been separated with alternative chiral agents as disclosed by Jursic.

Further, in so employing the conventional chiral resolving agents of the claims, a salt complex between the compound and the chiral agent, i.e. product of claim 13, is expected to form since it was taught by Jursic that such amine salt complex formation is through hydrogen bonding (p.1714).

Applicants argued that the difference of amide containing resolving agent of Jursic et al. would not motivate one skilled in the art to choose an alternative "acid' resolving agent. This is not persuasive because not only Jursic explicitly taught that the amides are acidic in function but also it is well recognized in the art that choosing an optical resolving agent is in its recognition of optical property. The well recognized tartaric acid as claimed is analogous to its amide i.e. the tartranilic acid (see US4,410,700 col.9, lines 41-42 and structural delineation of tartranilic acid) being acidic optical resolving agent. Therefore, artisan having ordinary skill in the optical resolution field would find that operability of the resolving agent disclosed by Jursic would motivate the picking and choosing of alternative resolving agent with expectation of reasonable success in separation of enantiomers.

(C)

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jursic et al. In view of Berrang et al. CA 97; Ohashi et al. CA 104; or Vanderplas et al. CA 118 further in view of Patrick et al.

The finding of prima facie obviousness over Jursic in view of Berrang, Ohashi or Vanderplas as delineated supra is also applicable here and incorporated here by reference. The instant claim 12 differs from the Jursic process in that an additional step for making the compounds from a pyridinyl precursor was incorporated. This precursor addition is also an conventional step in preparation of the claimed compounds as disclosed by Patrick (see p.487). Therefore, one having ordinary skill in the art who is well aware of all the pertinent art in the field, would be motivated to start the preparation from an alternative readily available precursor material as taught by Patrick with reasonable expectation of success.

(D)

Claims 1-8, 10-13 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,936,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claims of the instant application included the patented claims and no acceptable terminal disclaimer has been filed.

(11) Response to Argument

The following arguments were presented by Appellants:

A. The Jursic reference does not disclose the claimed methods because:

1. No disclosure of the claims "acid resolving agent",

2. No disclosure of the claimed salt formation,

3. No disclosure of the claimed salt isolation.

B. The examiner has not identified any motivation for combining the respective teachings of the cited reference

The Examiner's position to the above arguments is:

A. The Jursic reference did disclose ***all*** the elements of the claims as it was clearly identified in the rejection of Paper No. 10 that the exact enantiomers (p.1712 fig. 1), the acidic resolving agents (p.1712 structure and p.1713 line 1 acidic functionality of the resolving agents), the salt formation (p.1714 lines 2-3 below table 1) and salt isolation (p.1713 fig. 3 and lines 6-7 satisfactory separation of complexes with agent 2).

Therefore, contrary to Appellants' allegation that Jursic et al. did not disclosed all the elements of the claims, it was evidenced that every elements of the claims are found in Jursic.

The arguments of Appellants that--

--the "acid resolving agents" are limited to *"compounds whose hydrogen moieties can be removed by the recited piperadyl acetamides"* ;

--the "salts" can not be complexes but only limited to those exemplified in the specification;

--the separation of products as evidenced by identifiable peaks using analytical skill can not constitute isolation of each components.

During patent examination, the examiners were clearly instructed that claims must be given their broadest reasonable interpretation consistent with the specification (MPEP 2111), and unless specifically defined, "plain meaning" referring to the meaning given to the term by those of ordinary skill in the art, must be given to the claims (MPEP 2111.01).

The terms "acidic resolving agents" "salts" and "isolation" in the claims which are drawn to process of making, must be given the broadest plain meaning given by those of ordinary skill in the art and in consistent with the specification i.e. operating a chemical synthesis. The claims are drawn to process of preferential synthesis of d-threo piperidinyl acetamide. In interpreting the term "acid resolving agent" it must be in context of a process which is "process" of proton/electron activity. Since Jursic p.1713 explicitly taught that the resolution is based on the "acidity" of amide hydrogen, the anticipation is proper. Please note that the Jursic reference is describing a "process" of chemical synthesis which lead to separated identifiable complexes of piperidinylacetamide and resolving agents. The acidic functionality was defined by Jursic et al. who are artisans in the field (see Jursic p.1713), and such definition is consistent with the current understanding of acid-base reaction. The disclosure of Jursic et al. with respect to acid-base reaction product i.e. a salt complex and the separation/isolation of such complex are all consistent with the current textbook teaching of the field (see Morrison and Boyd of record and Concise Encyclopedia chemistry is hereby provided for Appellant's convenience). Appellants' insistence that the term acidic and salt must be interpreted being only those limited to the examples of the specification are reading into the claims limitations from the specification. As a matter of fact, the process incorporating the limitation of the particular salts as disclosed by the specification has been allowed and Appellants made no comments on the double patenting of the obviousness type issue of record.

The problem of Appellants' argument relied upon that acid-base reaction must involve proton removal is erroneous. Chemists have long defined that acid-base reaction are not limited to mere removal of hydronium ions (see Morrison and Boyd, especially p.34). The allegation that *"Thus 'acids' according to the claims are not compounds that simply include 'removable' hydrogen moieties, but, rather, compounds whose hydrogen moieties can be removed by the recited piperadyl acetamides"* is reading limitation of the specification into the claims. Please note that the claims are drawn to acidic resolving

agents which did not encompass any connotation that any hydrogen moiety is removed but rather that the functionality of the agent is acidic, i.e. as described by Jursic p.1713.

The problem of appellants' argument relied upon that a salt must be white crystals pours into one's hand is erroneous. The acid-base reaction product is the acid-base complex (see Morrison and Boyd and Encyclopedia) . Whether the complex can be obtained in form of a white crystals is a solubility issue of where the complex is formed. If the solvent where the complex is formed has a low solubility of the complex, then the salt will precipitate out as solids, otherwise, the complex will stay as soluble complex. Therefore, based on the current concept of salt formation, the "separate" identifiable complexes of Jursic met the claimed scope of forming isolated salt. Please note that whether the salt is obtained in solid is a solubility issue, not whether an isolated complex is formed. If Appellants read the limitation of the examples from the specification into the claims so that it is limited to only solid salts separated from the reaction media, then, Appellants must place such limitation in the claims and address the double patenting issue of record.

B. One having ordinary skill in the art would find the limitation of the dependent claims prima facie obvious in view of the state of the art teaching of enantiomeric separation of optical isomers.

Jursic taught the claimed process and disclosed the alternative choices of solvents being alcohol (p.1713, lines 6-7) and suggested that with the demonstration of Jursic's resolution of enantiomers, other resolving agent with multipoint interaction can be used to provide discrimination among enantiomers (see p.1711 last paragraph). Berrang, Ohashi or Vanderplas provided evidence that reagents encompassed by formula of claim 7 i.e. dibenzoyl tartaric acids are conventional choices for amine compounds analogous to the instant claims. Therefore, one having ordinary skill in the art would find the picking and choosing of alternative chiral reagent conventional for analogous compounds, optimization with solvents of the Jursic process prima facie obvious. The additional steps of starting material or salt formation of the process are also conventionally operated in making of the exact threo-piperidinylacetamide by Patrick et al. See p.487 amide and acetate. The incorporation in the process of conventional steps particularly known for the making of the specific compound is prima facie obvious. The motivation would be that the particularities of the Patrick reference is directed solely for the making of the claimed compound.

C. The allowed process of US 5,936,091 is a species of the instant claims 1-7, 8-13 and 15. Appellants made no comments that why the "judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)" does not apply to the instant case and should not be addressed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Celia Chang
Primary Examiner
Art Unit 1625

May 30, 2002

Conferees

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